REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

A. Status of the Claims

As a result of the present amendment, claims 1-5 and 13 are presented for continued prosecution. Claims 6-12 have been withdrawn from consideration.

B. The Invention

The present invention, as defined by the amended claims, includes a process for manufacturing a fibrin membrane from blood plasma. In one of the novel aspects of the invention, a physiological coagulating agent is added to blood plasma, and the transudate is removed from a blood clot using a physiological absorbing agent.

The process of the present invention has several advantages. First, the process can be performed quickly and with less expense, by avoiding centrifugation and other complex machinery associated with prior art methods for cicatrization and hemostasis. Second, the membrane obtained by the process of the invention is compatible with humans and animals, because the plasma is obtained from humans and animals. In addition, the process of the invention produces a membrane that has high adhesiveness and adequately isolates a wound, which promotes the cicatrization process. Fourth, the membrane obtained by the process of the invention can be preserved in a sterile package until the membrane is applied onto a wound (see page 2, lines 6-25 of the application).

C. Claim Objections, Claim Rejections under 35 U.S.C. § 112, and Claim Amendments

Multiple dependent claim 5 was objected to for being in improper form. Claim 5 has been amended to depend upon claim 1.

The Examiner rejected claim 1 stating that it is unclear whether the claim is directed to a process for manufacturing a membrane or a clot. The invention is directed to processes for manufacturing a membrane (see page 1, lines 4-5, page 2, line 1, page 2, lines 22-23, page 3, lines 13-14, and page 4, lines 10-18, for example). For clarification, claim 1 has been amended to recite that a membrane is formed when the transudate is removed. Support for this

amendment can be found, for example, in lines 15-16 on page 4 of the application.

Claim 1 has also been amended to correct some of the grammatical inconsistencies when translating the application into English.

Claims 1 and 2 have been amended to correct the antecedence issues raised by the Examiner in the final two paragraphs on page 3 of the Office Action.

In claim 5, the phrase "low boiling" has been deleted.

The recitation of ethanol in propane-triol in claim 5 has been deleted and presented as new dependent claim 13.

It is believed that the amendments to the claims overcome the claim objections and claim rejections under § 112.

D. Claim Rejections under 35 U.S.C. § 103(a)

Claims 1-5 had been rejected as being unpatentable over Beretta (WO 98/58689) in view of Stroetmann (U.S. 4,427,651).

Beretta had been cited to teach a method for making a fibrin clot/membrane, wherein plasma is contacted with calcium chloride. Stroetmann had been cited to teach methods for making fibrin clots/membranes wherein plasma is coagulated with an agent followed by washing with sodium chloride. The Examiner stated that it would be obvious to practice the claimed method steps based on the teachings of Beretta and Stroetmann.

In order to maintain an obviousness rejection under 35 U.S.C. § 103(a), the differences between the claimed invention and the prior art must be obvious to a person of ordinary skill in the art at the time the claimed invention was made. Applicant respectfully submits that the claimed invention is not obvious based on the combination of Beretta, Stroetmann and the knowledge of those in the art for at least the following reasons.

1. Beretta and Stroetmann do not teach or suggest removing a transudate from a blood clot using a physiologically absorbing agent

The claimed invention includes a process for manufacturing a fibrin membrane. Some known prior art processes for promoting hemostasis apply a liquid fibrin glue onto a wound. Such processes are undesirable because the glue sometimes overflows before the fibrin solidifies. In contrast thereto, the membrane of the claimed invention has properties which are preferable to

liquid fibrin glues, because the membrane has high adhesiveness thereby adequately isolating the wound (see page 2, lines 14-17 of the present application).

Claim 1 recites that the transudate is removed from the blood clot using a physiologically absorbent agent (the physiologically absorbent agent can be an inorganic salt, such as sodium chloride, see claims 2 and 3). The transudate removal step is important, because the blood clot takes the appearance of a fibrous membrane as a result of the transudate removing step (lines 10-18 on page 4 of the present application).

The Examiner did not cite Beretta to teach the transudate removal step of claim 1. Applicant has also studied Beretta and found that this teaching is absent. The Examiner cited col. 9, lines 36-45 of Stroetmann to teach washing with sodium chloride, sodium chloride being one of the claimed absorbent agents used to remove the transudate.

Applicant respectfully disagrees with the Examiner's reading of Stroetmann. The sodium chloride washing step in col. 9 of Stroetmann is not a step employed to prepare a membrane. Instead, the sodium chloride washing step is a testing step performed on the final product to determine a) thrombin activity, b) fibrin linkability, and c) coagulation activity (see col. 9, lines 16-68 of Stroetmann).

For example, Stroetmann explains in lines 20-30 of col. 9 that a dry powdery mixture is dissolved in sodium chloride to measure thrombin activity. This is a testing step, not a step used to prepare a membrane. Moreover, Stroetmann produces a sprayable composition, not a membrane, the sprayable composition including the aforementioned powdery mixture (see col. 2, lines 34-51 and claim 1). Stroetmann does not mention a process for producing a membrane as claimed in the present application. Stroetmann therefore does not teach step b) of process claim 1, or a method for producing a fibrin membrane in general.

Similarly, Stroetmann's second test measures fibrin linkability, while his third test measures coagulation activity. Sodium chloride is employed in both tests (see col. 9, lines 37-40 and lines 50-53). However, similar to the thrombin activity test described above, measuring the fibrin linkability and the coagulation activity are tests, not steps used to prepare a membrane. Again, Stroetmann does not mention a process for producing a membrane using sodium chloride.

Applicant therefore respectfully submits that the claimed process would not be obvious to those in the art, because Beretta and Stroetmann do not teach those in the art to manufacture a fibrin membrane by removing a transudate from a blood clot using a physiologic absorbing agent

as recited in step b) of claim 1.

2. Beretta and Stroetmann do not teach or suggest the fibrin membrane manufacturing process of the claimed invention

The Examiner stated on page 4 of the Office Action that Beretta and Stroetmann teach methods for making fibrin clots/membranes. Applicant respectfully disagrees.

The steps recited in claim 1 employed to manufacture a fibrin membrane of the present invention easily and inexpensively obtain wholly sterilized membranes having physical and structural properties wherein the membranes and flexible, moldable, adhesive and soakable in organic solutions (page 3, lines 11-17 of the application). It is simple for those in the art to perform the process steps recited in claim 1, which results in a process that is easy to execute and commercially desirable due to the low cost resulting from the absence of the use of expensive equipment.

Beretta is directed to a kit that is used to prepare a fibrin glue (page 1, lines 5-7). Fibrin glue is a different product than a fibrin membrane. For instance, as summarized in the present application, fibrin glues tend to overflow when applied to a wound, before the glue solidifies (page 1, lines 24-30 of the present application). In contrast, fibrin membranes are highly adhesive and are capable of completely isolating a wound (page 2, lines 14-17 of the present application). The fibrin glue of Beretta is therefore different than the fibrin membrane recited in claim 1, and Beretta therefore does not teach the method of manufacturing a fibrin membrane recited in claim 1.

Applicant notes that Examples 5 and 6 of Beretta teach the production of "membranes of fibrin glue". However, the "membranes of fibrin glue" are produced using very expensive equipment, such as centrifuges and cryoprecipitators (see page 6, lines 17-18, line 28, line 31 and line 33). The "membranes of fibrin glue" taught in Examples 5 and 6 of Beretta differ from the present invention, because the "membranes of fibrin glue" are not manufactured by removing a transudate from a blood clot using an absorbent agent (such as sodium chloride) as recited in step b) of claim 1. Instead, an absorbent agent is not employed. Applicant reminds the Examiner that since claim 1 is a process claim, step b) of claim 1 should be given significant weight, and step b) must be obvious to support a rejection, even if it is assumed, for arguments sake, that the final products of the present invention and Beretta are the same.

Moreover, as summarized in the present application, the use of expensive equipment, such as the centrifuge and cryoprecipitator employed in Examples 5 and 6 of Beretta, can lead to a product that costs about one thousand dollars (page 1, lines 21-23 of the present application). On the contrary, since the process of the claimed invention does not employ such expensive equipment, the resulting fibrin membrane can cost about five dollars, which is a fraction of the cost when expensive equipment is employed. It should therefore be considered that step b) of claim 1, which recites that the transudate is removed using an absorbent agent (such as sodium chloride), is a significant advantage over Examples 5 and 6 of Beretta, which employ expensive equipment, not an absorbent agent to remove the transudate. In addition, as mentioned above, the claimed invention is commercially desirable because the process is easy to perform and expensive machinery is unnecessary. The non-obviousness of the process steps recited in claim 1 should therefore be considered as a whole, because the combination of the process steps produces a membrane that has commercial advantages over the art.

Similarly, Stroetmann does not teach the fibrin membrane manufacturing process of the claimed invention. Instead, Stroetmann is directed to a sprayable composition (see col. 2, lines 34-51 and claim 1). A sprayable composition differs from a membrane, because, similar to the glue of Beretta, the sprayable composition of Stroetmann tends to overflow from the wound before it solidifies.

In addition, the sprayable composition of Stroetmann includes a powdery mixture, a fibrinolysis inhibitor, and an anhydrous solvent, among other things (col. 2, lines 34-51). The sprayable composition of Stroetmann is not produced by adding a coagulating agent to blood plasma as recited in step a) of claim 1, and removing the transudate using an absorbent agent as recited in step b) of claim 1. Instead, the solid powdery mixture of Stroetmann is suspended in a solvent to produce a sprayable composition. No mention is made to the specific process steps a) and b) of claim 1. Applicant again reminds the Examiner that steps a) and b) must be obvious to support a rejection, since claim 1 is a process claim which recites process steps to produce a fibrin membrane.

In summary, neither Beretta nor Stroetmann teach a process for producing a fibrin membrane, wherein the process employs steps a) and b) of claim 1. Even assuming that such steps are singularly known, it is respectfully submitted that the invention is non-obvious, because the combination of steps claimed in the present application produces a membrane that has

commercial advantages over the art in both simplicity of manufacture and final cost. Applicant therefore respectfully submits that the claimed process would not be obvious to those in the art.

E. Fees

This Response is being filed within the shortened statutory period for reply. No fee is believed to be due. If, on the other hand, it is determined that fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

F. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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